General

Guideline Title

Lipoprotein biomarkers and risk of cardiovascular disease: a Laboratory Medicine Best Practices (LMBP) systematic review.

Bibliographic Source(s)

Sandhu PK, Musaad SM, Remaley AT, Buehler SS, Strider S, Derzon JH, Vesper HW, Ranne A, Shaw CS, Christenson RH. Lipoprotein biomarkers and risk of cardiovascular disease: a Laboratory Medicine Best Practices (LMBP) systematic review. J Appl Lab Med. 2016 Sep;1(2):214-29. [63 references] PubMed

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Recommendations

Major Recommendations

Definitions for the ratings of overall strength of evidence and recommendation categories are provided at the end of the "Major Recommendations" field.

Apolipoprotein (Apo) B

Laboratory Medicine Best Practice (LMBP) Working Group (WG) Recommendation (Apo B)

Based on the moderate evidence of effectiveness, lipoprotein apo B measure is recommended to improve the risk prediction for cardiovascular events when added to other traditional risk factors for the populations at risk (e.g., men >35 years, women >45 years, and younger adults ≥20 years old with multiple risk factors for cardiovascular disease [CVD], in ambulatory and inpatient settings). This recommendation is based on consistently favorable results from 3 good quality and 1 fair quality studies.

Apo A-I

LMBP WG Recommendation (Apo A-I)

Because of the insufficient available evidence, no recommendations could be made for or against the effectiveness of apo A-I practices to predict the CVD events.

Apo B/Apo A-I

LMBP WG Recommendation (Apo B/Apo A-I Ratio)

According to the LMBP methods, based on the moderate evidence of effectiveness the lipoprotein apo B/apo A-I ratio is recommended to improve the risk prediction for cardiovascular events when added to other traditional risk factors for the populations at risk (e.g., men >35 years, women >45 years, younger adults ≥20 years old with multiple risk factors for CVD, in ambulatory and inpatient settings). This recommendation is developed based on evidence from 4 good and 3 fair quality studies (see Table 2 in the original guideline document).

Non-High-Density Lipoprotein Cholesterol (Non-HDL-C)

LMBP WG Recommendation (Non-HDL-C)

Because of the insufficient available evidence, no recommendations could be made for or against the effectiveness of non-HDL-C practices to predict the CVD events (see Table 3 in the original guideline document).

Definitions

Overall Strength of Evidence Ratings*

High: Adequate volume of consistent evidence of substantial healthcare quality impact from studies without major limitations.

Moderate: Some evidence of consistent substantial healthcare quality impact from studies without major limitations; OR an adequate volume of consistent evidence of moderate healthcare quality impact from studies without major limitations.

Suggestive: Limited evidence of moderate healthcare quality impact from a small number of studies without major limitations; OR the quality of some studies' design and/or conduct is limited.

Insufficient: Any estimate of an effect on healthcare quality impact is too uncertain.

*These rating categories have their basis in the work of Guyatt et al.; they were modified to reflect both the quality of the evidence and effect size observed, rather than attempting to anticipate the impact of future potential evidence. The modified definitions for these categories are modeled after the U.S. Preventive Services Task Force.

Recommendation Categories

Recommend: High or moderate for improving healthcare quality. The practice should be identified as a "best practice" for implementation in appropriate care settings, taking into account variations and applicability in implementation and/or care settings.

No recommendation for or against: Suggestive or insufficient. A potentially favorable impact on healthcare quality is not of sufficient size, or not sufficiently supported by evidence to indicate that it should be identified as a "best practice" for implementation in appropriate care settings.

Recommend against: High or moderate for adversely affecting healthcare quality. The practice should not be identified as a "best practice" for implementation because it is not likely to result in more good than harm.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Cardiovascular disease (CVD) events

- Ischemic heart disease
- Congestive heart failure
- Stable angina
- Unstable angina
- Myocardial infarction
- CVD death

Guideline Category

Evaluation

Prevention

Risk Assessment

Screening

Technology Assessment

Clinical Specialty

Cardiology

Family Practice

Internal Medicine

Pathology

Preventive Medicine

Intended Users

Advanced Practice Nurses

Clinical Laboratory Personnel

Health Care Providers

Physician Assistants

Physicians

Guideline Objective(s)

To evaluate the available evidence to compare the incremental utility of apolipoprotein and non-high-density lipoprotein (HDL) lipid biomarkers to the traditional lipid measures (e.g., total cholesterol [TC], triglyceride [TG], high-density lipoprotein cholesterol [HDL-C]) and other nonlipid standard risk factors (e.g., smoking status, high blood pressure, type 2 diabetes) for risk prediction of cardiovascular disease (CVD) events

Target Population

Patients with no previously diagnosed cardiovascular disease (CVD) or diabetes at baseline in ambulatory (including primary, specialty care) and inpatient settings who are at risk to develop cardiovascular CVD events, including men (>35 years), women (>45 years), and younger adults (≥20 years) with multiple cardiovascular risk factors for CVD

Interventions and Practices Considered

Measurement of the following lipid biomarkers in addition to traditional factors to calculate cardiovascular risk:

- Apolipoprotein (apo) B
- Apo A-I (no recommendation made)
- Apo B/apo A-I ratio
- Non-high-density lipoprotein cholesterol (non-HDL-C) (no recommendation made)

Major Outcomes Considered

Improvement in the 10-year risk prediction of cardiovascular disease (CVD) events (e.g., myocardial infarction, ischemic heart disease, and CVD death) upon adding the nonstandard biomarker

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Searches of Unpublished Data

Description of Methods Used to Collect/Select the Evidence

Ask (A-1): Review Question and Analytic Framework

Review Question

What practices are effective at improving the risk prediction (or risk estimation) for cardiovascular disease (CVD) events among the populations at risk, specifically ischemic heart disease, congestive heart failure, angina, myocardial infarction, and CVD death, when supplemented to the traditional lipid (e.g., total cholesterol [TC], low-density lipoprotein [LDL], triglycerides [TG], and high-density lipoprotein [HDL]) and nonlipid (e.g., age, sex, smoking status, and blood pressure) risk factors? This review question is addressed in the context of an analytic framework as depicted in Figure 1 in the original guideline document. The following were the relevant Population, Intervention/Practice, Comparator, and Outcome (PICO) elements considered for this review.

Population

- Men (>35 years)
- Women (>45 years)
- Younger adults (≥20 years) with multiple cardiovascular risk factors for CVD
- No previously diagnosed CVD or diabetes at baseline
- In ambulatory (including primary, specialty care) and inpatient settings

Interventions

Practices using nonstandard lipoprotein measurements in addition to the existing traditional risk factors (e.g., TC, TG, low-density lipoprotein cholesterol [LDL-C], high-density lipoprotein cholesterol [HDL-C], age, sex, smoking status, and blood pressure) for calculating cardiovascular risk assessment. The following lipid biomarkers were considered for this review:

- Apolipoprotein (apo B)
- Apo A-I
- Apo B/apo
- A-I ratio
- Non-HDL-C

Comparison

Practices using traditional risk factors (e.g., TC and HDL-C, age, sex, smoking status, and blood pressure) alone to calculate CVD risk prediction.

Outcome

Improvement in the 10-year risk prediction of CVD events (e.g., myocardial infarction, ischemic heart disease, and CVD death) upon adding the nonstandard biomarker. Studies with follow-up period <10 years were still included in the review but were penalized in the study quality rating because of type 1 censoring of the findings.

Inclusion/Exclusion Criteria for Studies to Be Included in This Review

Inclusion Criteria

To meet the eligibility criteria for this review, a study had to (a) address one or more of the proposed practices of interest in the context of CVD outcomes; (b) target populations in the studies who met the population criteria—that is, at-risk populations described above, with no previously diagnosed CVD or diabetes; (c) report the outcome(s) of interest—that is, improvement in the 10-year risk prediction of CVD events (e.g., myocardial infarction, CVD death) due to the addition of 1 of the 4 practices; and (d) provide comparison data to calculate the effectiveness of practices of interest (e.g., pre- and post-intervention data, concurrent comparison data).

In addition, interventions were considered to be included in this review if the biomarker of interest was added to a model or algorithm of the traditional lipid profile (e.g., TC, TG, HDL-C) and other risk factor (e.g., high blood pressure, cigarette smoking, diabetes, family history of premature heart disease, age, sex, diet, obesity, and physical inactivity) for predicting CVD risk. The practices were considered individually (e.g., the combination of apo B and non-HDL-C simultaneously added into a model was not considered a practice of interest), unless the results for the effectiveness of each practice was reported separately. A practice was considered effective if the fit of a model containing all traditional risk factors was significantly improved through the addition of a practice.

Exclusion Criteria

The exclusion criteria were as follows: (a) previously diagnosed CVD or symptomatic coronary artery disease at baseline and (b) previously diagnosed diabetes at baseline.

Acquire (A-2): Search for Evidence

A comprehensive electronic literature search was conducted to retrieve the relevant evidence published before and including July 2015. Three databases were used for a formal literature search: PubMed, CINAHL, and EMBASE (focusing on international biomedical literature). Details of the formal literature search strategy can be found in Supplemental Appendix C (see the online Data Supplement [see the "Availability of Companion Documents" field]). In addition, the systematic review team used other sources to locate relevant studies including hand searches (e.g., the citations from retrieved studies, Google scholar) and referrals from the experts in the field (e.g., expert panel team). To collect relevant unpublished data, researchers in the field, laboratories, and institutions were invited through personal requests and the Laboratory Medicine Best Practices (LMBP) website, but the review team did not receive any relevant unpublished data to be included in this review.

Number of Source Documents

A total of 5575 bibliographic records were retrieved from the literature search, of which 106 were identified from other sources (e.g., hand searches, referrals). A total of 5305 studies were excluded (2044 duplicates and 3261 were not relevant to the topic). The remaining 270 published studies were screened further, and 179 were excluded. The remaining 91 studies were subjected to full abstraction and quality assessment; finally, 9 independent published studies met the inclusion criteria and comprised the total body of evidence (see Figure 2 in the original guideline document for a search flow diagram).

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Overall Strength of Evidence Ratings*

High: Adequate volume of consistent evidence of substantial healthcare quality impact from studies without major limitations.

Moderate: Some evidence of consistent substantial healthcare quality impact from studies without major limitations; OR an adequate volume of consistent evidence of moderate healthcare quality impact from studies without major limitations.

Suggestive: Limited evidence of moderate healthcare quality impact from a small number of studies without major limitations; OR the quality of some studies' design and/or conduct is limited.

Insufficient: Any estimate of an effect on healthcare quality impact is too uncertain.

*These rating categories have their basis in the work of Guyatt et al.; they were modified to reflect both the quality of the evidence and effect size observed, rather than attempting to anticipate the impact of future potential evidence. The modified definitions for these categories are modeled after the U.S. Preventive Services Task Force.

Methods Used to Analyze the Evidence

Meta-Analysis

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Appraise (A-3): Screening, Data Abstraction, and Quality Scoring of Individual Studies

During the initial screening process, studies were excluded if they did not satisfy the inclusion criteria for this review as described. Each eligible study was abstracted and assessed for quality of execution by 2 independent reviewers. Data abstraction was conducted by using the standardized Laboratory Medicine Best Practices (LMBP) abstraction methods and abstraction form. All differences were resolved through consensus. After the full abstraction, each study was evaluated for quality scoring to minimize any issue related to internal and external validity using LMBP quality assessment methods (see the "Availability of Companion Documents" field).

Details on the rating process of individual studies can be found elsewhere (see the "Availability of Companion Documents" field). Each study was classified into 1 of 3 quality ratings: good (8–10 score), fair (5–7 score), and poor (≤4 score). Studies with poor quality ratings were excluded from the effect size metaanalyses and the overall practice evidence base. See Supplemental Appendix D (in the online Data Supplement; see the "Availability of Companion Documents" field) for the Evidence Summary Tables containing quality ratings for each study.

Analyze (A-4): Summarization of Results and Strength of the Effect Magnitude

Results from all included studies were variously reported risk ratios: odds ratios, relative risks, or hazard ratios. For the analyses purposes, these ratios were assumed to approximate the same measure of relative risk. Metaanalysis was performed to calculate the overall grand mean effect. A random-effects model was used for these statistics to perform metaanalysis because (a) not all the studies compared the same mixture of nontraditional lipid biomarkers to the traditional risk factors to improve the cardiovascular disease (CVD) risk prediction and (b) the long-term CVD risk prediction was based on different clinical CVD events in individual studies. To evaluate the effectiveness of these interventions, pooled point estimates across studies were expressed as an overall grand mean with confident intervals (CIs). When possible, all metaanalysis results were presented as forest plots, where the vertical line labeled "1" equals "no/minimal" difference between practices, and estimates to the right of the line favor the tested practice, i.e., improved risk prediction of CVD events due to the assessed practice. However, as apolipoprotein (apo) A-I levels inversely correlate with risk for CVD (i.e., high apo A-I levels are protective against future cardiovascular events), the effect estimates less than 1 were considered favorable for development of CVD risk prediction.

For the effectiveness strength rating, the point estimate from each study between ≤1 and ≤2.0 was considered as a "moderate" magnitude of effectiveness; and any point estimate >2.0 was considered a "substantial" magnitude of effect. Final conclusions and recommendations for the overall effectiveness were based on the criteria including number of studies, quality of available evidence, consistency of results, and magnitude of effect estimates. Criteria for these ratings are described in greater detail elsewhere (see the "Availability of Companion Documents" field).

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

This systematic evidence review was conducted using the Laboratory Medicine Best Practices (LMBP) Initiative's "A-6" systematic review

methods, which is reported in detail elsewhere (see the "Availability of Companion Documents" field) (LMBP™ Web site). In brief, the process includes formation of a review team that includes a review coordinator, data abstractors, Centers for Disease Control and Prevention (CDC) liaison, and subject matter experts (expert panel team) with the expertise in the area of cardiovascular medicine, laboratory management, and evidence review methods. The team worked under the oversight of the LMBP Workgroup. The results of the evidence-based best practice are presented to and approved by the LMBP Workgroup team.

Final conclusions and recommendations for the overall effectiveness were based on the criteria including number of studies, quality of available evidence, consistency of results, and magnitude of effect estimates. Criteria for these ratings are described in greater detail elsewhere (see the "Availability of Companion Documents" field).

Rating Scheme for the Strength of the Recommendations

Recommendation Categories

Recommend: High or moderate for improving healthcare quality. The practice should be identified as a "best practice" for implementation in appropriate care settings, taking into account variations and applicability in implementation and/or care settings.

No recommendation for or against: Suggestive or insufficient. A potentially favorable impact on healthcare quality is not of sufficient size, or not sufficiently supported by evidence to indicate that it should be identified as a "best practice" for implementation in appropriate care settings.

Recommend against: High or moderate for adversely affecting healthcare quality. The practice should not be identified as a "best practice" for implementation because it is not likely to result in more good than harm.

Cost Analysis

No eligible economic evaluations were identified for analysis of cost-effectiveness.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

The results of the evidence-based best practice are presented to and approved by the Laboratory Medicine Best Practices (LMBP) Workgroup team.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Available evidence showed that nontraditional lipid biomarkers apo B and apo B/apo I ratio can improve the risk prediction for cardiovascular events after controlling for the traditional risk factors for the populations at risk. However, because of insufficient evidence, no conclusions could be made for the effectiveness of apo A-I and non-HDL-C lipid markers to predict the CVD events.

Potential Harms

The use of additional lipid biomarkers could require an additional venipuncture. All venipuncture procedures pose a minimal risk to clinical staff of needle stick injury and exposure to infectious or other harmful agents. In addition, patients identified at intermediate risk to develop cardiovascular disease (CVD) events may become candidates for unnecessary additional testing to better stratify risk and for aggressive medical therapy (e.g., lipid lowering, blood pressure control) for secondary CVD prevention.

Qualifying Statements

Qualifying Statements

Qualifying Statements

Study Limitations

The scope and clinical relevance of this review is confined to cardiovascular disease (CVD) events and excludes stroke, which has been included in the outcome for CVD risk assessment in the recent national guidelines for assessment of cardiovascular risk. Most of the evidence for this review is from prospective studies with populations having a single race/ethnicity, thus limiting generalizability. However, across the studies, there was a variety of findings supporting the need to develop population-specific risk prediction systems. In some cases, the follow-up period was <10 years, which may introduce bias into the case ascertainment process. However, this concern was compensated during the quality scoring of these studies. Differences in inherent or baseline risk status may arise from the type of population used in the studies (community based vs clinic based), which may affect study results. In addition, the restriction to English language studies may also introduce bias.

Several studies summarized in this review did not control for variations in measurement method and interindividual variation—for example, this review assumed that all biomarker tests used in individual studies performed at the same level of analytical quality. The impact of these differences on the outcome of this review is not known.

Disclaimer

The findings and conclusions of this article are those of the authors and do not necessarily represent the views of the Centers for Disease Control and Prevention (CDC).

Implementation of the Guideline

Description of Implementation Strategy

Considerations for Implementation

Apolipoprotein (apo) B is measured mainly by immunonephelometric or immunoturbidimetric assays. Efforts to improve variability among these assays have been made by harmonizing measurements using a thoroughly characterized immunoassay. Because apo B is a well-characterized analyte, it has the potential of being standardized and linked to the International System of Units (SI system), which is not possible with low-density lipoprotein cholesterol (LDL-C), which is often only indirectly measured and harmonized to a thoroughly characterized ultracentrifugation method. Like apo B, apo A-I is mainly measured with immunonephelometric or immunoturbidimetric assays. These assays are being harmonized to a thoroughly characterized immunoassay, while high-density lipoprotein cholesterol (HDL-C) assays are standardized to a thoroughly characterized ultracentrifugation method. Non-HDL-C is simply calculated as the difference between total plasma cholesterol and HDL-C. Since it can be calculated directly from routine lipid tests, it does not incur additional cost, making it more readily available. Since non-HDL-C does not depend on triglycerides, it can be calculated from nonfasting samples.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Staying Healthy

IOM Domain

Effectiveness

Identifying Information and Availability

Bibliographic Source(s)

Sandhu PK, Musaad SM, Remaley AT, Buehler SS, Strider S, Derzon JH, Vesper HW, Ranne A, Shaw CS, Christenson RH. Lipoprotein biomarkers and risk of cardiovascular disease: a Laboratory Medicine Best Practices (LMBP) systematic review. J Appl Lab Med. 2016 Sep;1(2):214-29. [63 references] PubMed

Adaptation

Not applicable: the guideline was not adapted from another source.

Date Released

2016 Sep

Guideline Developer(s)

Centers for Disease Control and Prevention - Federal Government Agency [U.S.]

Laboratory Medicine Best Practices - Independent Expert Panel

Source(s) of Funding

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Role of Sponsor

The funding organizations played no role in the design of study, choice of enrolled patients, review and interpretation of data, or preparation or approval of manuscript.

Guideline Committee

Laboratory Medicine Best Practices (LMBP) Cardiovascular Disease (CVD) Biomarkers Expert Panel

LMBP Workgroup

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Financial Disclosures/Conflicts of Interest

Authors' Disclosures or Potential Conflicts of Interest

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Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Available from the Journal of Applied Laboratory Medicine (JALM) Web site .

Availability of Companion Documents

The following are available:

- Sandhu PK, Musaad SM, Remaley AT, Buehler SS, Strider S, Derzon JH, Vesper HW, Ranne A, Shaw CS, Christenson RH. Lipoprotein biomarkers and risk of cardiovascular disease: a Laboratory Medicine Best Practices (LMBP) systematic review. Supplemental data. Appendices A-C. Available from the Journal of Applied Laboratory Medicine (JALM) Web site .
- Sandhu PK, Musaad SM, Remaley AT, Buehler SS, Strider S, Derzon JH, Vesper HW, Ranne A, Shaw CS, Christenson RH. Lipoprotein biomarkers and risk of cardiovascular disease: a Laboratory Medicine Best Practices (LMBP) systematic review. Supplemental data. Appendix D. Available from the JALM Web site .
- Christenson RH, Snyder SR, Shaw CS, Derzon JH, Black RS, Mass D, Epner P, Favoretto AM, Liebow EB. Laboratory Medicine Best Practices: systematic evidence review and evaluation methods for quality improvement. Clin Chem. 2011 Jun;57(6): 816-25. Available from the Clinical Chemistry Web site .

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on January 26, 2017. The information was verified by the guideline developer on April 4, 2017.

Copyright Statement

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